

## **REMARKS**

Applicants appreciate the thorough examination of the present application as evidenced by the Office Action dated March 6, 2006 (hereinafter, "the Office Action"). Applicants further appreciate the withdrawal of the claim rejections as stated in the Office Action on page 4.

Applicants have canceled, without prejudice, Claims 7 and 27 herein. Applicants have amended Claims 1, 10, 21 and 28 to include a recitation directed to "pharmaceutically acceptable salts thereof." Support for these claim amendments can be found in the specification on page 8, lines 13-14 as originally filed. Claims 1, 4-6, 10, 13-18, 21, 24-26, 28, 29 and 32-34 are pending in the present application, and Applicants respectfully submit that these claims are patentable for at least the reasons discussed below.

### **I. Interview Summary**

Applicants extend their gratitude to Examiner Barbara P. Badio, Ph.D. for the telephonic interview conducted on May 30, 2006 with Applicants' representative, Shawna Cannon Lemon.

The participants discussed the Response to Arguments section of the present Office Action on pages 5-7. In particular, the Examiner provided further clarification regarding the Examiner's concerns regarding the recitation "conjugate thereof."

In view of the helpful and constructive dialog expressed during this interview, Applicants set forth the claim amendments and additional remarks presented herein in support of the patentability of the pending claims.

### **II. Claim Rejections Under 35 U.S.C. § 112, First Paragraph**

The rejection of Claims 33 and 34 under 35 U.S.C. § 112, first paragraph, as lacking written description has been maintained. More specifically, the Office Action states that "[a]pplicant cannot claim specific subject matter, such as a specific compound, not disclosed by the original specification (see MPEP §706.03(o)). Thus, even if one agrees with applicant's argument, the broad disclosure of glucuronide as a potential substituent does not provide support for the presently claimed compounds." Office Action, page 3. Applicants respectfully disagree.

Turning to the cited portion of the Manual of Patent Examining Procedure (MPEP), MPEP §706.03(o) refers the reader to MPEP §2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter. MPEP §2163.05 states that in order to comply with the written description requirement of 35 U.S.C. §112, first paragraph, "each limitation must be expressly, implicitly or inherently supported in the originally filed disclosure." Section 2163.05 further provides various case scenarios that tested whether introduction of claim changes presented a violation of the written description requirement. Applicants respectfully submit that there is no *per se* prohibition against a "broad disclosure" serving as the basis for support for a claim to a particular species. Instead, a fair reading of these cases leads to the conclusion, as set forth by the Federal Circuit, that "[e]ach case must be decided on its own facts in terms of what is reasonably communicated to those skilled in the art." *In re Wilder*, 222 USPQ 369, 372 (Fed. Cir. 1984).

Regarding the compounds presented in Claims 33 and 34, these compounds are at least reasonably communicated to those skilled in the art where the disclosure of glucuronide as a substituent provides support for the presently claimed compounds, wherein  $\text{NaC}_6\text{H}_8\text{O}_7$  is an example of a glucuronide. Moreover, the spectral data provides further support for the presently claimed compounds. Accordingly, the compounds presented in Claims 33 and 34 are at least expressly, implicitly or inherently supported in the originally filed disclosure as would be understood by one skilled in the art through the detailed description and figures of the application, including the spectral data provided therein.

At least in view of the foregoing remarks and those previously made of record, Applicants respectfully submit that Claims 33 and 34 are supported by the present specification, and Applicants respectfully request that claim rejections under 35 U.S.C. §112, first paragraph, be withdrawn.

### **III. Claim Rejections Under 35 U.S.C. § 103**

Claims 1, 4-7, 10, 13-18, 21 and 24-29 and 32 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of IL 25265 to Harnik (hereinafter, "Harnik"). More specifically, the Office Action states that "Harnik teaches several estrogenic estrane derivatives such as 3,6-dimethoxy-estra-1,3,5,7,9-pentaen-17-ol and 3,6-dimethoxy-estra-1,3,5,7,9-pentaen-17-

one. The instant claims differ from the reference by reciting a chemically pure form." Office Action, page 4 (citation omitted).

As previously noted, Harnik merely discusses synthesis of particular estrogenic estrane derivatives. These derivatives and the reaction products described in the synthesis do **not** teach or suggest a substitution at the 3 position to provide the compounds recited in the pending claims. In particular, amended independent Claims 1, 10 and 21 recite, "R<sub>3</sub> is selected from the group consisting of hydrogen, sulfate and glucoronide." Harnik, however, discusses compounds having a **methoxy** group at the 3 position of a 1,3,5,6,8 estrapentaene backbone. Harnik neither teaches nor suggests the claimed compounds having the recited substituents at the 3 position.

Accordingly, Harnik does not teach the claimed compounds. Thus, the presently claimed compounds do not represent a chemically pure form of the compounds described in Harnik. Instead, the presently claimed compounds are distinct compounds as compared to the compounds described in Harnik, and are also distinct, chemically pure compounds.

In view of discussions with the Examiner on May 30, 2006 regarding the recitation "conjugates thereof," and further in an effort to expedite prosecution, Applicants have amended the recitations of Claims 1, 10 and 21 to delete the recitation "conjugate thereof."

Accordingly, Applicants respectfully submit that Harnik: (a) fails to disclose all the claim recitations of the present invention; (b) fails to suggest any modification of the compounds presented in the reference in order to arrive at the present claim recitations; and (c) fails to provide a reasonable expectation of success of making and/or using the claimed invention at least in view of the foregoing. Thus, Applicants respectfully request that the rejection of Claims 1, 4-6, 10, 13-18, 21, 24-26, 28, 29 and 32 under 35 U.S.C. §103(a) be withdrawn for at least these reasons.

### CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any

Attorney Docket No. 9448-16CT2

In re: Hill et al.

Serial No.: 10/628,057

Filed: July 23, 2003

Page 12 of 12

event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

In the event that additional fees are necessary to allow consideration of this paper, such an extension is also hereby petitioned for under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully Submitted,



Shawna Cannon Lemon  
Registration No. 53,888

**USPTO Customer No.: 20792**

Myers Bigel Sibley & Sajovec, P.A.

Post Office Box 37428

Raleigh, NC 27627

Telephone (919) 854-1400

Facsimile (919) 854-1401

**CERTIFICATION OF ELECTRONIC TRANSMISSION  
UNDER 37 CFR § 1.8**

I hereby certify that this correspondence is being transmitted electronically to the U.S. Patent and Trademark Office on June 5, 2006.



Sarah E. Abraham

Date of Signature: June 5, 2006